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10/520,087	12/28/2004	Xi Jiang	CHM-007M	9197
2686X	7590	10/31/2007	EXAMINER	
HASSE & NESBITT LLC			LI, BAO Q	
8837 CHAPEL SQUARE DRIVE			ART UNIT	PAPER NUMBER
SUITE C			1648	
CINCINNATI, OH 45249				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/520,087	JIANG ET AL.
	Examiner	Art Unit
	Bao Qun Li	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 August 2007.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 9,10,15,16 and 19-33 is/are pending in the application.  
 4a) Of the above claim(s) 9,10 and 19-21 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 15-16 and 22-33 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group II, claims 15-16 and 22-33 in the scope of oligosaccharide and F2G in the reply filed on August 27, 2007 has been acknowledged.
2. Claims 15-16 (2) and 22-33 in the scope of oligosaccharide and F2G are considered.

### *Claim Objections*

The disclosure is objected to because of the following informalities:

Please spell out the complete words of NVL and F2G and Fuc- $\alpha$ 1-2 etc cited in the claims 15-16 when they first appeared in the claims.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 15-16 and 22-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are not in the possession for having a composition comprising at least one compound comprising oligosaccharide that inhibit the binding of a NVL with antigen histo-blood group antigen preferably having the structure of F2G.
5. Whether Applicants have the possession of claimed invention is related to the factors set forth below: 1). Level of skill in the art; 2). Method of making it; 3). Complete or partial structure; 4). Physical and/or biological properties; and 5). Correlation between structures.
6. In the instant case, Applicants do not described that they have isolated or purified or synthesize any oligosaccharide compound that inhibits the binding of a NVL with antigen histo-blood group H antigen preferably having the structure of F2G. Applicants have only described

that they identify that NVL capsid protein binds to the group of human blood histo-blood groups of antigens, and few antibodies that bind different blood histo antigens as well as inhibit the virus binding to the target cells.

7. While they only describe a functional of a polysaccharide, no complete or partial structure of such polysaccharide molecule has been disclosed by Applicants in the instant Application. Consequently, the relationship between the structured and physiological function is not known.

8. Applicants are reminded that the written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the ad to make and use the invention. The courts have concluded that the specification must demonstrate that the inventors had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.Zd 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 1 19 F.3d 1559, 43 U.S.P.Q.Zd 1398 (Fed. Cir. 1997). *Amgen Inc. F. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.Zd 1016-1031 (C.A.F.C. 1991). *Fiers v. Stzgano*, 25 U.S.P.Q.Zd 1601-1607 (C.A.F.C. 1993). *In re Bell*, 26 U.S.P.Q.Zd 1529-1532 (C.A.F.C. 1993). The significance of conception and reduction to practice was further addressed by the court in *Fiers v. Sugano* where it was emphasized that "[c]onception is a question of law, reviewed de novo on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated, thus, regardless of complexity or simplicity of method of isolation employed, conception of a DNA, like conception of any chemical substance, requires definition of that substance other than by its functional utility."

9. Moreover, the case law has also made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588,

591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). Thus, a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds, but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

10. In the instant case, while the method of making a oligosaccharide that inhibits the binding to NVL with a native blood group antigens of a human host may be possible or enabled, it makes no reference to an antibody in question. Thus, the case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. 35 USC 112 requires *inter alia* that "a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention."

11. To this context, Applicants do not have the possession for the claimed product.

#### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 15-16 and 22-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Adler et al. (The Journal of Biol. Chem. 1995, Vol. 270, No. 10, pp. 5164-6171).

14. Adler et al. teach a composition comprising a saccharide compound GalNAc conjugated with BSA, which is same as the claimed Fuc- $\alpha$ 1-3 in view of the explanation of Fuc- $\alpha$ 1-2 cited

in the specification page 20) that can competitively inhibit the E-histolytica lectin binding to the E-histolytica membranes. Adler et al. also provide variety of saccharide inhibitors that can competitively inhibit the E-histolytica lectin binding to the E-histolytica membranes with said saccharide inhibitor (See pages 5166-5169. Therefore, the claimed invention is anticipated by the cited reference.

15. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.
16. Also regarding the limitation of inhibiting the binding to NVL, the functional limitation of the claims product is inherently possessed if the claimed product has same structural limitation as that of the prior art.

***Claim Rejections - 35 USC § 102/103***

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 15-16 and 22-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 2002/0019991A1 or US patent 6,045,854A).

20. US 2002/0019991A1 or US patent 6,045,854A prove a composition comprising at least one oligonucleotide including flcosyl  $\alpha$ 1 galcoside gloside (See claims 1-5 of (991A1) or

Examples 3-8 in "854A). Therefore, claims 15-16 and 22-30 are anticipated by the cited references.

21. Or alternatively, it would have been obvious for a person with ordinary skill in the art to be motivated modify the concentration to get a better biological effect because the modification of the incubation time or concentration within the range is generally recognized as being within the level of the ordinary skill in the art, *In re Rose*, 105 USPQ 237 (CCPA 1995) because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the workable ranges involves only routine skill in the art, *In re Aller*, 105, USPQ 233. Hence, the claimed invention as a whole is *prima facie* obvious absence unexpected results.

22. Regarding the particular limitation for inhibiting NVL, Applicants' attention is directed to MPEO 2105 cites: III. A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC. Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

23. Therefore, claimed invention as a whole is *prima facie* obvious absence unexpected results.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li

10/28/2007

BAOQUN LI, MD  
PATENT EXAMINER